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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,881	12/30/2004	Tetsuya Sakata	10921.0268USWO	7393
52835 7590 04/12/2010 HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902				
EXAMINER				
DOUGHERTY, SEAN PATRICK				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/519,881

Applicant(s)

SAKATA ET AL.

Examiner

SEAN P. DOUGHERTY

Art Unit

3736

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This is the FINAL Office action based on the 10/519881 application filed 12/30/2003.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Response to Amendment

The amendment(s) filed 12/16/2009 by the Applicant in response to the previous Office action mailed 07/16/2009 have been considered by the Examiner. The Examiner acknowledges:

- Claims numbered 1-26 including:
 - Pending claim(s) 15 and 21-26;
 - Amended claim(s) 15 and 21; and
 - Cancelled claim(s) 1-14 and 16-20.

The Applicant's amendments have overcome the 35 U.S.C. 112, second paragraph rejections in the previous Office action.

The rejection(s) in the previous Office action of claim(s) 15 and 21-26 is/are maintained. The following new/reiterated ground(s) of rejection(s) is/are set forth below:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15 and 21-24 rejected under 35 U.S.C. 102(b) as being anticipated by US 7,500,967 to Thorley et al. (hereinafter "Thorley").

Regarding claim 15, Thorley discloses a cam mechanism for rotating a lancet relative to a cap that covers a lancing element of the lancet, the cam mechanism comprising comprising a cylindrical housing (118) best seen in Fig. 8, a movable member (115) best seen in Fig. 2 contained in the housing (col. 3, ll. 35-36) for moving reciprocally in first and second directions parallel to a longitudinal axis of the housing (note that elements 116 and 117 allow for moveable member 115 to move in first and second directions parallel to a longitudinal axis of housing 118), the movable member holding the lancet and configured to allow the lancet to rotate (col. 1, ll. 44-48; col. 8, ll. 22-29) relative to a cap (14) that covers the lancing element of the lancet (note that needle end 14 covers the lancing element when the lancing element is fully retracted) a first groove (123) inclined relative to the axis of the housing and a second groove (117) connected to the first groove (col. 4, ll. 27-28) and extending linearly in parallel to the axis of the housing (note that first groove extends linearly in parallel to the axis of the housing), the first and the second grooves being provided at the movable member, and a protrusion (122) provided at the movable member (col. 4, ll. 25-26), the protrusion

extending into the first groove and the second groove (col. 5, ll. 1-2), where the protrusion moves in the first groove when the movable member moves in the first direction, and moves in the second groove when the movable member moves in the second direction. Note a first direction of moveable member moves the protrusion through the first groove (turning) and a second direction moves the protrusion in a second direction (movement along the longitudinal axis) through the second groove.

Regarding claim 21, Thorley discloses a lancing device comprising a cylindrical housing (118) best seen in Fig. 8, a lancet holder (115) that holds a lancet (413; col. 1, ll. 44-48) having a lancing element covered by a cap (14; note that needle end 14 covers the lancing element when the lancing element is fully retracted), the lancet holder being reciprocally movable along a longitudinal axis of the housing (col. 8, ll. 22-29), a moving mechanism (116) for advancing the lancet holder along the longitudinal axis of the housing, and a cam mechanism (123) for converting a retracting movement of the lancet holder along the longitudinal axis of the housing into rotation of the lancet holder and the lancet relative to the cap (col. 1, ll. 44-48; col. 8, ll. 22-29).

Regarding claim 22, note that the lancet holder and the lancet of Thorley are not rotatable relative to each other when the protrusion is within the moving mechanism (116) as the lancet holder may only move along the longitudinal axis in this position. The cam mechanism is capable of causing the lancet holder and the housing to rotate at the same time, therefore, the cam mechanism is capable of causing the lancet holder to rotate together with the lancet.

Regarding claim 23, Thorley discloses where the cam mechanism includes a first groove (123) which provided on the housing and is inclined relative to the longitudinal axis of the housing, and a protrusion (122) which is provided on the lancet holder and is fitted in the first groove. Note that since the housing and the lancet holder touch, the first groove, while part of the lancet holder, may be considered on the housing. Similarly, the protrusion, while part of the housing, may be considered on the lancet holder.

Regarding claim 24, Thorley discloses where the cam mechanism further includes a second groove (117) connected to the first groove (col. 4, ll. 27-28) and extending in parallel to the longitudinal axis of the housing, and where the protrusion passes through the second groove when the lancet holder advances (col. 6, ll. 60-63).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25 and 26 rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,500,967 to Thorley et al. (hereinafter "Thorley"), as applied to claim 21 above, in view of US 5,989,917 to McAleer et al. (hereinafter "McAleer").

Regarding claims 25 and 26, Thorley discloses the claimed invention as set forth in claim 21, above. Thorley does not expressly disclose a holding portion for removably holding an analyzer used for analyzing a sample taken by a piercing process and a control circuit for analyzing the sample using the analyzer.

McAleer is a reference in analogous art that discloses a holding portion (1) for removably holding an analyzer ("disposable test strip"; see abstract) taken by a piercing process and a control circuit (52) for analyzing the sample using the analyzer. One having an ordinary skill in the art at the time the invention was made would have found it obvious to include the holding portion, analyzer and control circuit of McAleer with the device of Thorley, since the predictable result of performing an electrochemical analysis of the amount of an analyte such as glucose as established in McAleer's abstract on a blood sample taken by the device of Thorley would ensue.

Response to Arguments

The Applicant's arguments filed 12/16/2009 have been fully considered by the Examiner, below:

With respect to the rejection of claim 15 as being anticipated by Thorley, the Applicant argues at page 5 of the arguments that "nowhere does Thorley disclose or

suggest that the plunger 115 is configured so as to allow a lancet to rotate. The Examiner disagrees and respectfully submits that Thorley does disclose a plunger configured so as to allow a lancet to rotate. The Examiner notes at col. 1, ll. 44-47 of Thorley, a grasping mechanism is disclosed between the plunger and the needle. When these two elements are connected, it is inherently disclosed, via the rotation disclosed at col. 8, ll. 22-29, that the needle rotates along with the plunger as the plunger is withdrawn.

Further, the Applicant argues with respect to the rejection of claim 15 at page 5 of the arguments that "nowhere does Thorley disclose or suggest a cap that covers a lancing element of a lancet". The Examiner disagrees and respectfully submits that the broadest reasonable interpretation of the claim renders element 14 in Thorley to anticipate the claimed invention. Note that element 14 (needle end of Thorley) covers the lancing element with the lancing element, by way of the plunger, is fully retracted.

With respect to the rejection of claim 15 as being anticipated by Thorley, the Applicant argues at page 6 substantially similar points as addressed above in the rejection of claim 15. The Examiner has already addressed these points in response to the arguments of claim 15, above.

Therefore, the rejection of claims 15 and 21 as being anticipated by Thorley is maintained as presented above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Friday, 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Sean P. Dougherty/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736